

**Translation**

**PCT**

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C1-A0111P	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP02/10743	International filing date ( <i>day/month/year</i> ) 16 October 2002 (16.10.02)	Priority date ( <i>day/month/year</i> ) 16 October 2001 (16.10.01)
International Patent Classification (IPC) or national classification and IPC A61K 45/00, 31/445, A61P 35/00		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 16 October 2002 (16.10.02)	Date of completion of this report 21 April 2003 (21.04.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1 - 7	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 7	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 7	YES
	Claims		NO

## 2. Citations and explanations

- Document 1: Biochemistry, 10 April 2001, Vol. 40, No. 14, pages 4454 to 4458
- Document 2: Pharmaceutical Research, June 1998, Vol. 15, No. 6, pages 816 to 818
- Document 3: International Journal of Cancer, 15 October 2000, Vol. 88, No. 2, pages 274 to 280
- Document 4: Cancer Research, 01 February 1998, Vol. 58, No. 3, pages 519 to 525
- Document 5: WO 97/19919 A1 (C & C Research Laboratories), 05 June 1997
- Document 6: Bioorganic & Medicinal Chemistry Letters, September 2000, Vol. 10, Issue 17, pages 1939 to 1942

Claims 1-7

The invention set forth in claims 1-7 is novel and involves an inventive step in relation to documents 1-6 cited in the international search report.

Documents 1-6 do not disclose or suggest suppressing the proliferation of cells (particularly carcinoma cells) by inhibiting the functions of peptide transporters.

In addition, the invention set forth in claims 1-7 exhibits industrial applicability.

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## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

As set forth in the claims, the scope of the "peptide transporter-inhibiting substance" that is an active component of the "cell proliferation inhibitor" can be considered to include an extremely large number of chemical substances. At the time the present application was filed, however, the fact that inhibiting the activity of the peptide transporter will definitely suppress the proliferation of cells was not common technical knowledge, and it was not known whether the sulfamide derivatives represented by general formula (1) actually exhibited a peptide transporter-inhibiting activity or not (rather, said derivatives were only known to exhibit an anti-thrombin activity, as indicated in the document WO 97/19919 A1 (C & C Research Laboratories), 05 June 1997 for example). Such being the case, the only chemical substance presented in the description that is considered to exhibit both a peptide transporter-inhibiting activity and an cell proliferation-inhibiting action is the substance that the applicant refers to by the name "AT-264."

As a result, the inventions set forth in the claims cannot be said to be fully supported by the description.